

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0881101	(X3) Date Survey Completed 09/18/2026
Name of Provider or Supplier Hines Dermatology Associates Inc	Street Address, City, State 555 Pleasant St, Attleboro, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the CASPER 96D report, lack of Proficiency Testing (PT) records, and staff interview with the Laboratory Director (LD), the laboratory failed to enroll in a CMS-approved PT program for the regulated analyte 0025, Mycology. Findings include: 1. Record review on 9/18/2026 of the CASPER 96D 'CLIA Application and Survey Summary' report revealed: a. No scores were reported for the regulated analyte 0025, Mycology, for 2024 Events 2 and 3; 2025 Events 1, 2, and 3; and 2026 Events 1 and 2 to date. b. The last scores reported to CMS for the regulated analyte 0025, Mycology was for 2024 event 1. 2. Record review on 9/18/2026 of the laboratory's CMS form 116 revealed the laboratory performs fungal cultures using Dermatophyte Test Medium (DTM). 3. Record review on 9/18/2026 of the laboratory's DTM PT records revealed no documentation of PT participation for regulated analyte 0025, Mycology, for 2024 Events 2 and 3, 2025 Events 1, 2, and 3 and 2026 Events 1 and 2 to date. 4. Staff interview with the LD on 9/18/2026 at 9:30 AM confirmed the above findings. The LD stated, "We stopped doing PT when our lab tech left and we stopped identifying to genus and species." 5. The laboratory performs 65 DTM cultures annually in the subspecialty of Mycology.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review, surveyor observation, and interview with the Laboratory Director (LD), the laboratory failed to ensure that expired media was not used when performing fungal cultures in the subspecialty of Mycology. Findings include: 1. Surveyor observation on 9/18/2026 at 10:15 AM of the contents of the laboratory's incubator revealed: a. A white a rack containing seven Dermatophyte Test Medium (DTM) patient cultures. b. All seven DTM vials were manufactured by Hardy Diagnostics, catalog number L27, lot number 675696, with an expiration date 6/13 /2026. 2. Record review on 9/18/2026 of the Hardy Diagnostics 'Instructions for Use' for DTM revealed, "The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below." 3. Record review on 9/18/2026 of the laboratory's DTM media quality control records revealed DTM media lot numbers have not been recorded since 6/5/2024, therefore, the surveyor was unable to determine the extent to which the expired DTM media had been used beyond the seven patient cultures observed. 4. During an interview on 9/18/2026 at 10:30 AM, the LD confirmed that the seven DTM patient cultures noted above were inoculated using expired DTM media. 5. The laboratory performs 65 DTM cultures annually in the subspecialty of Mycology.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, (OM) and the Laboratory Director (LD) , the laboratory failed to perform and document quality control (QC) of each lot and shipment of Dermatophyte Test Medium (DTM) culture slants prior to patient use, including inspection of the physical characteristics of the media and testing for sterility, ability to support growth,, select or inhibit specific organisms, and the production of the expected biochemical response in the subspecialty of Mycology. Findings include: 1. Record review on 9/18/2026 of the laboratory's 'Quality Control Records' manual revealed that QC for DTM culture slants had not been documented since 6/12/2024. There was no documentation indicating that the DTM culture slants were visually inspected, checked for sterility, or tested for their ability to support growth and produce the expected biochemical response. There were no QC records for 2025 or 2026 to date. 2. Record review on 9 /18/2026 of the laboratory's 'Quality Control Procedures' policy revealed: a. Upon receipt of media, laboratory personnel were required to mark the box with the date

received and inspect the media, documenting on the QC sheet any cracked bottles, unequal fill of bottles, cracked media, freezing, excessive bubbles, or contamination. b. The procedure required the media to be inoculated with stock cultures and incubated at room temperature for up to seven days to verify the expected growth. c. A handwritten notation on the procedure, dated 8/30/1993, stated, "NCCLS stickers provided with each lot of media acceptable on QC sheets. Six points QC above will still be recorded." 3. Record review on 9/18/2026 of the laboratory's Individualized Quality Control Plan for DTM media revealed the Quality Control Plan (QCP) specified that QC would be performed with each new lot and shipment of DTM media. 4. Interview with the OM and LD on 9/18/2026 at 11:00 AM confirmed the findings above. 5. The laboratory performs 65 DTM cultures annually in the subspecialty of Mycology.